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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,266	04/21/2005	Clifford J Woolf	00786/425002	8760
21559	7590	03/11/2009		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER POCHAS, CHRISTOPHER M	
			ART UNIT 4121	PAPER NUMBER
			NOTIFICATION DATE 03/11/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/510,266	Applicant(s) WOOLF, CLIFFORD J	
	Examiner Christopher Pochas	Art Unit 4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/14/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Office Action

- 1) Claims 1-30 are pending in the instant application.**
- 2) Priority is claimed to U.S. Provisional Application 60/376147. All claims gain the benefit of this priority claim.**

Non Final Rejection

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1- 5, 7-15, 17-25, and 27-30 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application 20030064122 A1.

Claims 1- 5, 7-15, 17-25, 27-30 U.S. Patent Application 20030064122 A1 (hereafter the 122 document) discloses the use of capsaicin in an oral (i.e. suitable for ingestion) therapeutic composition for the purpose of preventing abuse of the active agent or agents of that composition. Paragraph 13 of the 122 document discloses that the

Art Unit: 4121

capsaicin can be incorporated into the matrix of the tablet (i.e. mixed as per pending claims 11 and 21). Paragraph 1 of the 122 document reads, "The invention relates to pharmaceutical compositions which include systems to deter abuse. More specifically, the invention relates to compositions containing an effective amount of pharmaceutical compound and capsaicin or a capsaicinoid compound. Most specifically, the invention relates to a composition containing an effective amount of a pharmaceutical compound, and an amount of a capsaicin compound to deter intranasal, oral, and intravenous abuse while having little or no irritating effect when administered orally or transdermally as directed." Paragraph 2 of the 122 document narcotics as the therapeutic agent, specifically oxycodone, hydrocodone, and benzodiazepines. Paragraph 10 of the 122 document reads, "As is well known in the art, such dosage forms may contain a number of inactive ingredients such as fillers, excipients, and time release formulations (including sustained release, extended release, etc.)," thereby anticipating the controlled release limitation of the pending claims. Claim 22 of the 122 document has the controlled release formulation as well.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 4121

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 6, 16, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application 20030064122 A1, as applied to claims 1- 5, 7-15, 17-25, and 27-30 above, and further in view of U.S. Patent 5232684.

Claims 6, 16, and 26 The 122 document does not teach resiniferatoxin specifically, however it does teach capsaicinoids generally.

Paragraphs 3 and 30 of the detailed description of U.S. Patent 5232684 disclose that resiniferatoxin is a capsaicinoid, and the 122 document discloses that capsaicin, as well as capsaicinoids being useful in deterring abuse. It would have been prima facie obvious to one skilled in the art to substitute resiniferatoxin for the capsaicin in the combination therapy of the 122 teaching, because they are both art recognized capsaicinoid compounds, and the 122 document discloses its usefulness in deterring abuse when it is combined with a therapeutic agent.

Art Unit: 4121

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Pochas whose telephone number is (571)270-7722. The examiner can normally be reached on Monday to Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571)272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CMP/

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4121